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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Nut-0003

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09/04/2008

EXAMINER

ROBERTS, LEZAH

ART UNIT

PAPER NUMBER

1612

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/852,182	<b>Applicant(s)</b> HAMMAN ET AL.	
	<b>Examiner</b> LEZAH W. ROBERTS	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 37-44, 46-54 and 56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 37-44, 46-54 and 56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

This Office Action is in response to the Amendment filed May 23, 2008. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. This Action is made NON-FINAL.

### ***Claims***

#### **Claim Rejections - 35 USC § 102 – Anticipation (Previous Rejection)**

Claims 37-40, 43-50 and 53-56 were rejected under 35 U.S.C. 102(e) as being anticipated by Ojima et al. (US 7,029,717). The rejection is maintained in regards to claims 37-40, 43, 44 and 46. The reference is withdrawn in regards to claims 47-50 and 53-56.

#### **Applicant's Arguments**

Applicant argues the Example used by the Examiner in the instant rejection does not evaluate taste masking but examines only discoloration. No indication of a relationship between discoloration and a bitter metallic taste is indicated. The Examiner has shown no anticipation of the "taste masking" effect of sucralose at the levels disclosed and claimed by Applicant. Ojima et al. has used levels of sucralose far in excess of those claimed by Applicant. The sucralose level is further limited by claims to 15% of the amino acid weight as opposed to the 91 to 95% level disclosed by Ojima et

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al. in taste masking evaluation and the 83% level in protein hydrolysate discoloration experiments by Ojima et al. Such excesses of sucralose and its sweetness would dwarf the taste of a minor component, the amino acids in Examples 17, 34 and 35, and in no way mirror the completely unobvious use by Applicant as a taste masking agent at the levels claimed. Applicant has clearly pointed out that the compositions are vastly different from that of Ojima et al. and are not as, Examiner claims, "substantially the same as the compositions of the instant claims." The statement by Examiner, see Remarks page 7, is not true as shown in Applicant's Table 1, where neither sucralose, aspartame, sugar or saccharin masked the taste of the amino acid, arginine. Sugar did not mask the taste of arginine, even when used at an amount equal to that of the amino acid. This argument is partially persuasive and the rejection is withdrawn in regards to the method claims.

#### Examiner's Response

Although the Example does not evaluate taste masking, it is a composition that would exhibit similar properties as those recited in the instant claims. The reference teaches not less than 0.0001 parts by weight, this is the lower limit, not the higher limit. Therefore the compositions of the reference encompass the instant claims. The Examiner reminds Applicant that the instant claims not only recite a method for taste masking but also a composition, therefore the intended use of the composition or its components carries no weight in determining patentability. This is because the compositions of the reference, comprising sucralose and a protein hydrolysate or amino

acid, and therefore are substantially the same as the compositions of the instant claims. That being said the sucralose should be able to mask the taste of the protein hydrolysate or amino acid because the composition of the reference and the compositions of the instant claims are substantially the same. Although the reference does not disclose the sucralose as a taste masker, it is used as a sweetener and will improve the taste because it sweetens the compositions.

2) Claims 44-46 and 54-56 were rejected under 35 U.S.C. 102(e) as being anticipated by Liu et al. (US 6,773,730). This rejection is maintained in regards to claims 44, 46, 54 and 56.

#### Applicant's Arguments

Applicant argues the ratio of hydrolyzed zein ranges from 1 to 4 to 4 to 1, but does not fall within or near the level Applicant has claimed. It is further noted that Liu et al. were unaware of the masking ability of sucralose and teach away from its use as they point out at col. 7, lines 9-10, that the "preferred bitterness masking agent is malt" at a level of 5-50%. This argument is not persuasive.

#### Examiner's Response

Liu et al. teach sucralose comprises 0.1% to 0.3% of the chewing gum, which is the zein gum. It is not clear how the ratio recited by Applicant ranging from 1 to 4 to 4 to 1 was calculated. Based on the percentages disclosed by the reference, the reference encompasses the instant claims. Furthermore the claims recite a taste-masking agent, it

does not recite that the taste has to necessarily be a bitter-taste but encompasses an unpleasant taste. Therefore the sweeteners will add a sweet taste to the gum.

**Claim Rejections - 35 USC § 102 – Anticipation (New Rejection)**

Claims 37-44, 46-54 and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Inoue et al. (WO 00/24273 published May 4, 2000, English translation US 7,229,658).

Inoue et al. disclose sucralose as a masking agent for foods comprising proteins (col. 20, lines 5-20). The amount of sucralose used ranges from 0.0001 to 0.01% by weight relative to the food (col. 24, lines 28-35). It is also used to mask the taste of amino acid or peptides, which are disclosed to have bitter tastes. These amino acids include valine, leucine, methionine and leucine-isoleucine. The peptides encompass protein hydrolysates (col. 23, lines 10-20). The sucralose may comprise 0.0001 to 0.5% by weight based on 100% by weight of the composition (col. 44, lines 5-11). Sucralose may also be used to mask the taste of preservatives used in food such as glycine, milt protein, and poly-lysine. Sucralose is added in a concentration ranging from 0.001 to 10 parts by weight of the preservative (col. 68, lines 38-49). The reference anticipates the instant claims insofar as it discloses a composition and a method for masking the taste of amino acids and proteins comprising sucralose.

**Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejection)**

Claims 42 and 52 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ojima et al. (US 7,029,717) in view of Newsholme et al. (US 5,639,731). The rejection is maintained in regards to claim 42 and withdrawn in regards to claim 52.

**Applicant's Arguments**

Applicant argues that Example 45 does not evaluate taste masking but examines only discoloration of the sucralose. No indication of a relationship between discoloration and a bitter metallic taste is indicated. Ojima et al. do not use sucralose as a taste masking agent at the levels disclosed and claimed by Applicant. Applicants have limited their claims to 15% of the amino acid weight as opposed to the 91 to 95% level disclosed by Ojima et al. in taste masking evaluation and the 83% level in protein hydrolysate discoloration experiments by Ojima et al. When the equivalent of 1 gram of amino acid (methionine in Ojima et al.'s Example 17) is placed with a sweetener equivalent to 3000 g of sugar, Applicant agrees with examiner that no bitter taste would be noted, simply because of the dilution effect. However, Applicant has shown that a 10 to 20 to 1 ratio, where it would be obvious to anyone, skilled or not, that only the very bitterest principles would not be diluted out beyond taste, is not equivalent to Applicant's claims which are completely unobvious. The compositions of the instant claims are not the same as the compositions of the reference. This argument is partially persuasive and the rejection is withdrawn in regards to the method claim 52.

Examiner's Response

As discussed above the amount of amino acid or protein hydrolysate disclosed by the reference is the lower limit. The amount of amino acid or protein hydrolysate may exceed that of the sucralose as exemplified in Example 45. Even though this is an example for discoloration, it still encompasses the compositions of the instant claims. See Examiner's response above in response to the arguments for Ojima et al. above.

Claims 37-44, 46-54 and 56 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/  
Examiner, Art Unit 1612

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612